

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference RLL-492WO	FOR FURTHER ACTION	see Form PCT/ISA/220 as well as, where applicable, item 5 below.
International application No. PCT/IB2005/000420	International filing date (day/month/year) 18/02/2005	(Earliest) Priority Date (day/month/year) 19/02/2004

Applicant

RANBAXY LABORATORIES LIMITED

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the language, the international search was carried out on the basis of the International application in the language in which it was filed, unless otherwise indicated under this item.
- The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. Certain claims were found unsearchable (See Box II).3. Unity of invention is lacking (see Box III).

4. With regard to the title,

- the text is approved as submitted by the applicant.
- the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- the text is approved as submitted by the applicant.
- the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the **drawings** to be published with the abstract is Figure No. _____

- as suggested by the applicant.
- as selected by this Authority, because the applicant failed to suggest a figure.
- as selected by this Authority, because this figure better characterizes the invention.

- b. none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IB2005/000420

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

The present invention relates to an extended release formulation that includes a drug capable of dissociating into a valproate ion, from about 15% to about 50% w/w of a high viscosity grade hydroxypropyl methylcellulose, and from about 0.1% to about 10% w/w of a low viscosity grade hydroxypropyl methylcellulose. The drug capable of dissociating into a valproate ion may be valproic acid and its pharmaceutically acceptable salts, esters, and amides.

A. CLASSIFICATION OF SUBJECT MATTER	A61K9/20	A61K31/19	A61P25/06	A61P25/08	A61P25/28
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used):
EPO-Internal, WPI Data, PAJ, CHEM ABS Data, MEDLINE, EMBASE, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 419 953 B1 (QIU YIHONG ET AL) 16 July 2002 (2002-07-16) cited in the application column 2, line 46 - line 65 column 5; table 1 column 8, line 31 - line 35 column 8 - column 9; table 4 ----- -/-	1-21

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document not published on or after the international filing date
- *L* document which may throw doubts on priority, claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *&* document member of the same patent family

Date of the actual completion of the international search

20 January 2006

Date of mailing of the international search report

09/02/2006

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	QIU Y ET AL: "ONCE-A-DAY CONTROLLED-RELEASE DOSAGE FORM OF DIVALPROEX SODIUM I: FORMULATION DESIGN AND IN VITRO/IN VIVO INVESTIGATIONS" JOURNAL OF PHARMACEUTICAL SCIENCES, AMERICAN PHARMACEUTICAL ASSOCIATION. WASHINGTON, US, vol. 92, no. 6, June 2003 (2003-06), pages 1166-1173, XP001161543 ISSN: 0022-3549 page 1167; table 1	1-21
A	US 5 019 398 A (DASTE ET AL) 28 May 1991 (1991-05-28) column 3 – column 4; example claims 1-5	1-21
A	WO 03/103635 A (RANBAXY LABORATORIES LIMITED; KUMAR, PRATIK; JAIN, GARISH, KUMAR; RAMP) 18 December 2003 (2003-12-18) page 2, line 14 – page 3, line 23 page 11; examples 1-7	1-21
P,A	WO 2004/071421 A (TEVA PHARMACEUTICAL INDUSTRIES LTD; TEVA PHARMACEUTICAL USA, INC; LICH) 26 August 2004 (2004-08-26) page 59; example 5 claims 1-120	1-21

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Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:
Although claim 21 is directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the composition.
2. Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out; specifically:
3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- The additional search fees were accompanied by the applicant's protest.
- No protest accompanied the payment of additional search fees.

Patent document cited in search report		Publication date		Patent family member(s)		Publication date
US 6419953	B1	16-07-2002	US ZA	6528091 B1 200104143 A		04-03-2003 04-12-2002
US 5019398	A	28-05-1991	AU AU CA DE DE EP FR NZ	623225 B2 4999890 A 2010427 A1 69000881 D1 69000881 T2 0385846 A1 2643556 A1 232649 A		07-05-1992 30-08-1990 27-08-1990 25-03-1993 12-08-1993 05-09-1990 31-08-1990 29-01-1991
WO 03103635	A	18-12-2003	AU BR CA CN EP JP US	2003240164 A1 0311642 A 2488691 A1 1671363 A 1513503 A1 2005533774 T 2004037880 A1		22-12-2003 01-03-2005 18-12-2003 21-09-2005 16-03-2005 10-11-2005 26-02-2004
WO 2004071421	A	26-08-2004		NONE		